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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,413	02/08/2001	Bernard J. Banks	PC10901A	9774

7590 02/14/2002  
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EXAMINER

HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 02/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/779,413

Applicant(s)  
Banks, et al.

Examiner  
Ray Henley

Art Unit  
1614



– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☐ Responsive to communication(s) filed on \_\_\_\_\_

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☒ Claim(s) 1-14 is/are allowed.

6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some\* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4

20) ☐ Other:

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**CLAIMS 1-14 ARE PRESENTED FOR EXAMINATION**

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Applicants' Preliminary Amendment filed June 19, 2001 and Information Disclosure Statement filed May 18, 2001 have been received and entered into the application. Accordingly, the specification at page 1, line 1 has been amended. Also, as reflected by the attached, completed copy of form PTO-1449, the cited references have been considered.

***Specification***

The present specification at page 15 is objected to as containing an illustration, i.e. graphical chart, which does not come within the purview of 37 C.F.R. 1.58(a). Applicants are required to submit such chart as formal drawings in accordance with 37 C.F.R. 1.81 or else amend the specification so as such illustrations are no longer present. See also MPEP 608.01(a) under the heading "ILLUSTRATIONS IN THE SPECIFICATION".

Should applicants elect to submit the illustration as formal drawings, the specification should also be amended by entering a section entitled "Brief Description of the Drawings".

***Claim Rejection - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. See, for example, *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967)

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and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966) respecting the impropriety of claims reciting "Use of..." and their dependents.

Accordingly, these claims have not been further treated on the merits.

Although claims 10-14 depend from a non-statutory claim, in order to expedite prosecution, the Examiner will treat these claims on the merits to the extent that the compound represented in claim 1 is read into claims 10-14.

### ***Claim Objections***

Claims 10-14 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The intent of the reliance on claim 1 is to incorporate the compound recited therein. This, however is improper because when a claim is depended upon, the entirety of the subject matter in that claim is incorporated. Applicants are required to either cancel the claims, amend the claims to place them in proper dependent form, or rewrite the claims in independent form.

### ***Claim Rejection - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harada et al. (EP 0 882 719)[Harada et al. '719] and Harada et al. (WO 98/57938)[Harada et al. '938].

Harada et al. '719 and '938 teach the presently claimed compounds as endothelin receptor antagonist (see the abstract for each). Harada et al. '719 further teach pharmaceutical compositions containing such compounds and their use in the treatment of a variety of endothelin mediated disorders (page 5, lines 35-48 and page 18, Example 2).

The differences between the above and applicants' claimed subject matter lie in that the references fail to highlight:

- (1) treatment of a companion animal; and
- (2) a pack containing the active agent and an instruction means.

However, to the skilled artisan, applicants' claimed subject matter would have been obvious because:

(1) the references teach that the compounds are effective for treating endothelin mediated disorders and the selection of a specific host in which to practice such treatment would have been a matter well within the purview of the skilled artisan; and

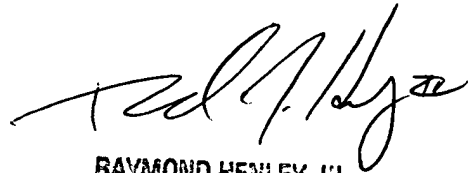
(2) in the pharmaceutical/veterinary art, it is routine, if not required, to include a package insert containing instructions for the use of the packaged pharmaceutical. The specific printed information is not material covered under patent laws, but rather copyright laws. Also, even if

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such were covered under patent laws, the limitation in the claim relating to the instructions would be seen as a statement of intended use for the claimed composition which does not impart any physical limitation to the composition that is not found in, or made obvious by the prior art.

Accordingly, for the above reasons, the claims are deemed to be properly rejected and none of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is (703) 308-4652.



RAYMOND HENLEY, III  
PRIMARY EXAMINER  
GROUP 1600

Henley; rjh  
February 11, 2002